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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/735,073	12/12/2000	Shirin Asina	ROGO-214.2-Cont	3402

24972 7590 04/04/2003  
FULBRIGHT & JAWORSKI, LLP  
666 FIFTH AVE  
NEW YORK, NY 10103-3198

*Remail*

EXAMINER

NAFF, DAVID M

ART UNIT PAPER NUMBER

1651

DATE MAILED: 04/04/2003

Please find below and/or attached an Office communication concerning this application or proceeding.



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## Office Action Summary

Application No.

09/35093

Applicant(s)

Asina whel

Examiner

M. J. J.

Group Art Unit

1651

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

### Status

- ☒ Responsive to communication(s) filed on 12/17/02
- ☐ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

### Disposition of Claims

- ☒ Claim(s) 54-122 is/are pending in the application.
- Of the above claim(s) 54-114 is/are withdrawn from consideration.
- ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- ☒ Claim(s) 115-122 is/are rejected.
- ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- ☐ Claim(s) \_\_\_\_\_ are subject to restriction or election requirement.

### Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
  - ☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been received.
  - ☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_.
  - ☐ received in this national stage application from the International Bureau (PCT Rule 1.7.2(a)).

\*Certified copies not received: \_\_\_\_\_

### Attachment(s)

- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s) \_\_\_\_\_
- ☐ Interview Summary, PTO-413
- ☐ Notice of Reference(s) Cited, PTO-892
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Other \_\_\_\_\_

Office Action Summary

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In a response of 12/17/02 to a restriction requirement of 11/25/02, applicants elected Group III claims 115-122 without traverse.

Claims 54-114 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made without traverse in Paper No. 8 of 12/17/02.

Claims examined on the merits are 115-122.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

10 ***Claim Rejections - 35 USC § 112***

Claims 121 and 122 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, 15 had possession of the claimed invention.

The specification fails to describe a composition as required by the claims as being an invention.

***Claim Rejections - 35 USC § 112***

Claims 115, 117 and 119-122 are rejected under 35 U.S.C. 112, first 20 paragraph, because the specification, while being enabling for the material that suppresses proliferation of cancer cells having a molecular weight of at least about 30 kd as disclosed in the specification at page 21, lines 17-20 when producing a conditioned culture medium as required by claims 115 and 117, does not reasonably provide enablement for 25 producing a material having a molecular weight below 30 kd that

suppresses proliferation of cancer cells as encompassed by the claims. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

5       The specification describes the material that suppresses proliferation of cancer cells as having a molecular weight of at least 30 kd, and does not indicate that material less than 30 kd can provide the function of suppressing proliferation of cancer cells.

***Claim Rejections - 35 USC § 103***

10       Claims 115-122 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jain et al (WO 97/36495).

      The claims are drawn to producing a conditioned culture medium which has a cancer cell proliferation-inhibiting effect by a process of entrapping cancer cells in a proliferation-restrictive selectively  
15 permeable structure, culturing the entrapped cancer cells in a culture medium where growth of the cells is restricted by the cells being entrapped so that the cells produce a material that suppresses proliferation of cancer cells which permeates the structure into the culture medium to produce the conditioned culture medium, and the  
20 conditioned medium is recovered. In claim 117, the recovered conditioned medium is frozen.

      Jain et al disclose encapsulating cancer cells in capsules such that proliferation of the cells is restricted during growth and the restricted cancer cells produce more of a cancer suppressing substance than when not  
25 restricted. The encapsulated cells can be implanted in a subject to

produce the substance and suppress cancer in the subject. Jain et al further disclose (page 16, lines 14-16) that the encapsulated cells can be cultured *in vitro* to produce diffusible products that move into the culture medium where the products can be collected.

5 In view of the *in vitro* culturing of entrapped cancer cells in a culture medium as disclosed by Jain et al, it would have been obvious to recover the culture medium after culturing since the culture medium would have been expected to contain the cancer cell suppressing material. Freezing the medium after recovery would have been obvious to preserve  
10 the medium.

Jain et al is a reference since parent application 08/745,063 is not enabling for the claimed invention, and Jain et al was published more than one year before filing the instant application.

***Double Patenting***

15 Claims 115-122 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-27 of U.S. Patent No. 6,224,912 B1. Although the conflicting claims are not identical, they are not patentably distinct from each other because the presently claimed invention of producing a conditioned culture medium  
20 would have been obvious from the claims of the patent requiring culturing entrapped restricted cancer cells in a culture medium to produce a material that suppresses cancer cell proliferation.

***Double Patenting***

Application Number: 09/735,073  
Art Unit: 1651

Page 5

Claims 115-122 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-8 of U.S. Patent No. 5,888,497 in view of Jain et al (WO 97/36495).

It would have been obvious to culture in a medium *in vitro* the entrapped cancer cells that produce a cancer suppressing material of the patent claims to allow the cancer suppressing material to diffuse into the medium and recover the medium as suggested by Jain et al (WO 97/36495) disclosing (page 16, lines 14-16) culturing restricted encapsulated cells *in vitro* in a culture medium to produce diffusible products that move into the culture medium where the products can be collected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David M. Naff whose telephone number is (703) 308-0520. The examiner can normally be reached on Monday-Thursday and every other Friday from about 8:30 AM to about 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, a message can be left on voice mail.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn, can be reached at telephone number (703) 308-4743.

The fax phone number is (703) 872-9306 before final rejection or (703) 872-9307 after final rejection.



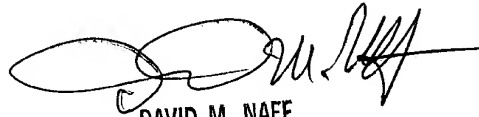
Application Number: 09/735,073  
Art Unit: 1651

Page 6

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

5

DMN  
10 3/22/03

  
DAVID M. NAFF  
PRIMARY EXAMINER  
ART UNIT 1265